



PATENT
Attorney Docket No. LEX-011
(4006/23)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Gillies et al. CONFIRMATION NO.: 8264
SERIAL NO.: 09/780,668 GROUP NO.: 1644
FILING DATE: February 09, 2001 EXAMINER: David A. Saunders
TITLE: ENHANCING THE CIRCULATING HALF-LIFE OF ANTIBODY-BASED
FUSION PROTEINS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- the requisite Statement is below, **OR**

- the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- (3) after the mailing date of a **final action or notice of allowance** but before the payment of the **issue fee**, **AND**
 - the requisite Statement is below, **AND**
 - the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Applicants believe no fee is required for entry and consideration of this paper. If a fee is required, please charge Deposit Account 20-0531.

Date: October 30, 2003
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Respectfully submitted,



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U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	07/348,237	5/5/89	Rosenblum et al.			
	A2	4,196,265	4/1/80	Koprowski et al.			
	A3	4,469,797	9/4/84	Albarella			
	A4	4,676,980	6/30/87	Segal et al.			
	A5	4,816,567	3/28/89	Cabilly et al.			
	A6	4,946,778	8/7/90	Ladner et al.			
	A7	5,019,368	5/28/91	Epstein et al.			
	A8	5,073,627	12/17/91	Curtis et al.			
	A9	5,114,711	5/19/92	Bell et al.			
	A10	5,116,964	5/26/92	Capon et al.			
	A11	5,199,942	4/6/93	Gillis			
	A12	5,225,538	7/6/93	Capon et al.			
	A13	5,225,539	7/6/93	Winter			
	A14	5,258,498	11/2/93	Huston et al..			
	A15	5,314,995	5/24/94	Fell, Jr. et al.			
	A16	5,349,053	9/20/94	Landolfi			
	A17	5,359,035	10/25/94	Habermann			
	A18	5,514,582	5/7/96	Capon et al.			
	A19	5,538,866	7/23/96	Israeli et al.			
	A20	5,541,087	7/30/96	Lo et al.			
	A21	5,543,297	8/6/96	Cromlish, et al.			
	A22	5,552,524	09/03/96	Basinski et al.			
	A23	5,585,089	12/17/96	Queen et al.			
	A24	5,609,846	3/11/97	Goldenberg			
	A25	5,624,821	4/29/97	Winter et al.			

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FORM PTO - 1449 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT			ATTORNEY DOCKET NO.: LEX-011 (4006/23) APPLICANT(S): Gillies et al. SERIAL NO.: 09/780,668 CONF.: 8264 FILING DATE: February 09, 2001 GROUP: 1644
	A26	5,639,725	6/17/97
	A27	5,645,835	7/8/97
	A28	5,650,492	7/22/97
	A29	5,667,776	9/16/97
	A30	5,679,543	10/21/97
	A31	5,691,309	11/25/97
	A32	5,709,859	1/20/98
	A33	5,719,266	02/17/98
	A34	5,726,044	3/10/98
	A35	5,728,552	3/17/98
	A36	5,733,876	3/31/98
	A37	5,756,461	05/26/98
	A38	5,759,551	6/2/98
	A39	5,770,195	6/23/98
	A40	5,800,810	9/1/98
	A41	5,807,715	9/15/98
	A42	5,827,516	10/27/98
	A43	5,837,682	11/17/98
	A44	5,843,423	12/1/98
	A45	5,854,205	12/29/98
	A46	5,856,298	1/5/99
	A47	5,858,347	1/12/99
	A48	5,885,795	3/23/99
	A49	5,886,178	3/23/99
	A50	5,888,772	3/30/99
	A51	5,922,685	7/13/99
	A52	5,994,126	11/30/99
	A53	6,080,409	6/27/00

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	A54	6,086,875	7/11/00	Blumberg et al.			
	A55	6,169,070	1/2/01	Chen et al.			
	A56	6,171,588	1/9/01	Carron et al.			
	A57	6,277,375	8/21/01	Ward			
	A58	6,348,192	2/19/02	Chan et al.			
	A59	6,406,689	6/18/02	Falkenberg et al.			

FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B1	0 158 198 A1	10/16/85	EP					Y
	B2	0 211 769 A2	2/25/87	EP					Y
	B3	0 256 714 A2	2/24/88	EP					Y
	B4	0 294 703 A2	12/14/88	EP					Y
	B5	0 308 936 B1	3/29/89	EP					
	B6	0 314 317 B1	5/3/89	EP					
	B7	0 318 554 B1	6/7/89	EP					
	B8	0 319 012 A2	6/7/89	EP					
	B9	0 326 120 B1	8/2/89	EP					Y
	B10	0 350 230 A2	1/10/90	EP					Y
	B11	0 375 562 B1	6/27/90	EP					Y
	B12	0 396 387 A2	11/7/90	EP					Y
	B13	0 439 095 A2	7/31/91	EP					Y
	B14	0 511 747 A1	11/4/92	EP					Y
	B15	0 601 043 B1	6/15/94	EP					Y
	B16	0 640 619 A1	3/1/95	EP					Y
	B17	0 668 353 A1	8/23/95	EP					Y
	B18	0 706 799 A2	4/17/96	EP					Y
	B19	0 790 309 A1	8/20/97	EP					Y

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FORM PTO - 1449					ATTORNEY DOCKET NO.: LEX-011 (4006/23)			
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT					APPLICANT(S): Gillies et al.			
					SERIAL NO.: 09/780,668		CONF.: 8264	
					FILING DATE: February 09, 2001		GROUP: 1644	
	B20	21725/88	3/23/89	AU				Y
	B21	93100115.3	7/14/93	CN				N
	B22	93100115.3	7/14/93	CN			Y	Y
	B23	37 12985 A1	11/3/88	DE				N
	B24	37 12985	11/2/88	DE			Y	Y
	B25	2 292 382 A	2/21/96	GB				Y
	B26	63-267278	11/4/88	JP				N
	B27	63-267278	11/4/88	JP			Y	Y
	B28	63-267296	11/4/88	JP				N
	B29	63-267296	11/4/88	JP			Y	Y
	B30	0 237 019 A2	9/16/87	EP			English counterpart of JP 63-267296	Y
	B31	WO 86/01533	3/13/86	PCT				Y
	B32	WO 88/00052	1/14/88	PCT				Y
	B33	WO 88/09344	12/1/88	PCT				Y
	B34	WO 89/02922	4/6/89	PCT				Y
	B35	WO 89/09620	10/19/89	PCT			Abstract in English	N
	B36	WO 90/03801	4/19/90	PCT				Y
	B37	WO 91/00360	1/10/91	PCT				
	B38	WO 91/04329	04/04/91	PCT				
	B39	WO 91/08298	6/13/91	PCT				
	B40	WO 91/13166	9/5/91	PCT				
	B41	WO 91/14438	10/3/91	PCT				Y
	B42	WO 92/02240	2/20/92	PCT				Y
	B43	WO 92/08495	5/29/92	PCT				Y
	B44	WO 92/08801	5/29/92	PCT				Y
	B45	WO 92/16562	10/1/92	PCT				Y
	B46	WO 93/03157	2/18/93	PCT				Y
	B47	WO 93/10229	5/27/93	PCT				Y

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	B48	WO 94/24160	10/27/94	PCT						Y
	B49	WO 94/25055	11/10/94	PCT						Y
	B50	WO 95/05468	2/23/95	PCT						Y
	B51	WO 95/21258	8/10/95	PCT						Y
	B52	WO 95/28427	10/26/95	PCT						Y
	B53	WO 95/31483	11/23/95	PCT						Y
	B54	WO 96/04388	02/15/96	PCT						Y
	B55	WO 96/05309	2/22/96	PCT						Y
	B56	WO 96/08570	3/21/96	PCT						Y
	B57	WO 96/31526	10/10/96	PCT						Y
	B58	WO 97/00317	1/3/97	PCT						Y
	B59	WO 97/15666	5/1/97	PCT						Y
	B60	WO 97/20062	6/5/97	PCT						Y
	B61	WO 97/24137	7/10/97	PCT						Y
	B62	WO 97/24440	7/10/97	PCT						Y
	B63	WO 97/26335	7/24/97	PCT						Y
	B64	WO 97/30089	8/21/97	PCT						Y
	B65	WO 97/33617	9/18/97	PCT						Y
	B66	WO 97/33619	9/18/97	PCT						Y
	B67	WO 97/34631	9/25/97	PCT						Y
	B68	WO 97/43316	11/20/97	PCT						Y
	B69	WO 98/00127	1/8/98	PCT						Y
	B70	WO 98/06752	2/19/98	PCT						Y
	B71	WO 98/28427	7/2/98	PCT						Y
	B72	WO 98/30706	7/16/98	PCT						Y
	B73	WO 98/46257	10/22/98	PCT						Y
	B74	WO 98/59244	12/30/98	PCT						Y
	B75	WO 99/02709	01/21/99	PCT						Y

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	B76	WO 99/03887	01/28/99	PCT					Y
	B77	WO 99/29732	6/17/99	PCT					Y
	B78	WO 99/52562	10/21/99	PCT					Y
	B79	WO 99/53958	10/28/99	PCT					Y
	B80	WO 99/60128	11/25/99	PCT					Y
	B81	WO 99/62944	12/09/99	PCT					Y
	B82	WO 99/66054	12/23/99	PCT					Y
	B83	WO 00/11033	3/2/00	PCT					Y
	B84	WO 00/34317	06/15/00	PCT					Y
	B85	WO 00/40615	7/13/00	PCT					Y
	B86	WO 00/68376	11/16/00	PCT					Y
	B87	WO 00/69913	11/23/00	PCT					Y
	B88	WO 00/78334 A1	12/28/00	PCT					Y
	B89	WO 01/07081 A1	2/1/01	PCT					Y
	B90	WO 01/10912- A1	2/15/01	PCT					Y
	B91	WO 03/015697 A2	2/27/03	PCT					Y

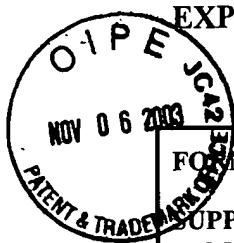
EXAM.
INIT. OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)

C1	Abaza et al., (1992), "Effects of Amino Acid Substitutions Outside an Antigenic Site on Protein Binding to Monoclonal Antibodies of Predetermined Specificity Obtained by Peptide Immunization," <u>Journal of Protein Chemistry</u> , 11:5:433-444.
C2	Abstract XP-002116766, (1996), "Prostaglandins, their inhibitors and cancer," <u>Prostaglandins, Leukotrienes and Essential Fatty Acids</u> , 54:2:83-94.
C3	Afonso et al., (1994), "The Adjuvant Effect of Interleukin-12 in a Vaccine Against Leishmania Major," <u>Science</u> , 263:235-237.
C4	Arenberg et al. (1996), "Interferon- γ -inducible Protein 10 (IP-10) Is an Angiostatic Factor That Inhibits Human Non-small Cell Lung Cancer (NSCLC) Tumorigenesis and Spontaneous Metastases," <u>J. Exp. Med.</u> , 184:981-992.

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FORM PTO - 1449 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTORNEY DOCKET NO.: LEX-011 (4006/23) APPLICANT(S): Gillies et al. SERIAL NO.: 09/780,668 CONF.: 8264 FILING DATE: February 09, 2001 GROUP: 1644
C5	Bacha et al., (1988), "Interleukin 2 Receptor-Targeted Cytotoxicity Interleukin 2 Receptor-mediated Action of a Diphtheria Toxin-related Interleukin 2 Fusion Protein," <u>J. Experimental Medicine</u> , 167:612-622	
C6	Bachelot et al., (March 1998), "Retrovirus-Mediated Gene Transfer of an Angiostatin-Endostatin Fusion protein with Enhanced Anti-Tumor Properties In Vivo," <u>Proceedings of the Annual Meeting of the American Association for Cancer Research</u> , 39:271, Abstract #1856.	
C7	Barnett et al., (1994), "Purification, characterization and selective inhibition of human prostaglandin G/H synthase 1 and 2 expressed in the baculovirus system," <u>Biochimica et Biophysica Acta</u> , 1209:130-139.	
C8	Baselga, et al., (1998), "Recombinant Humanized Anti-HER2 Antibody (Herceptin TM) Enhances the Antitumor activity of Paclitaxel and Doxorubicin against HER3/neu Overexpressing Human Breast Cancer Xenografts," <u>Cancer Research</u> , 58:2825-2831.	
C9	Batra et al., (1993), "Insertion of Constant Region Domains of Human IgG1 into CD4-PE40 Increases Its Plasma Half-Life," <u>Mol. Immunol.</u> , 30:379-386.	
C10	Becker et al., (1996), "An Antibody-Interleukin 2 Fusion Protein Overcomes Tumor Heterogeneity by Induction of a Cellular Immune Response," <u>Proc. Natl. Acad. Sci.</u> , 93:7826-7831.	
C11	Becker et al., (1996), "Eradication of human hepatic and pulmonary melanoma metastases in SCID mice by antibody-interleukin 2 fusion proteins," <u>Proc. Natl. Acad. Sci. USA</u> , 93:2702-2707.	
C12	Beutler et al., (1988), "Tumor Necrosis, Cachexia, Shock, and Inflammation: A Common Mediator," <u>Ann. Rev. Biochem.</u> , 57:505-518.	
C13	Bissery et al., (1997), "The Taxoids," in <u>Cancer Therapeutics: Experimental and Clinical Agents</u> , Teicher, ed., 175-193.	
C14	Bjorn et al., (1985), "Evaluation of Monoclonal Antibodies for the Development of Breast Cancer Immunotoxins," <u>Cancer Research</u> , 45:1214-1221.	
C15	Boehm et al., (1997), "Antiangiogenic therapy of experimental cancer does not induce acquired drug resistance," <u>Nature</u> , 390:404-407.	
C16	Boehm et al., (1998), "Zinc-Binding of Endostatin Is Essential for Its Antiangiogenic Activity," <u>Biochemical and Biophysical Research Communications</u> , 252:190-194.	
C17	Boissel et al., (1993), "Erythropoietin Structure-Function Relationships," <u>The Journal of Biological Chemistry</u> , 268:15983-15993.	
C18	Brooks et al., (1994), "Integrin $\alpha_v\beta_3$ Antagonists Promote Tumor Regression by Inducing Apoptosis of Angiogenic Blood Vessels," <u>Cell</u> , 79:1157-1164.	
C19	Buchli et al., (1993), "Structural and Biologic Properties of a Human Aspartic Acid-126 Interleukin-2 Analog," <u>Archives of Biochemistry and Biophysics</u> , 307:2:411-415.	
C20	Burgess et al., (1990), "Possible Dissociation of the Heparin-binding and Mitogenic Activities of Heparin-binding (Acidic Fibroblast) Growth Factor-1 from Its Receptor-binding Activities by Site-directed Mutagenesis of a Single Lysine Residue," <u>Journal of Cell Biology</u> , 111:2129-2138.	

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	C21	Canfield et al., (1991), "The Binding Affinity of Human IgG for its High Affinity Fc Receptor is Determined by Multiple Amino Acids in the CH2 Domain and Is Modulated by the Hinge Region," <u>Journal of Experimental Medicine</u> , 173:6:1483-1491.
	C22	Cao et al., (1996), "Kringle Domains of Human Angiostatin," <u>The Journal of Biological Chemistry</u> , 271:46:29461-29467.
	C23	Cao et al., (1997), "Kringle 5 of Plasminogen is a Novel Inhibitor of Endothelial Cell Growth," <u>The Journal of Biological Chemistry</u> , 272:36:22924-22928.
	C24	Capon et al., (1989), "Designing CD4 immunoadhesins for AIDS therapy," <u>Nature</u> , 337:525-531.
	C25	Caton et al., (1986), "Structural and functional implications of a restricted antibody response to a defined antigenic region on the influenza virus hemagglutinin," <u>The EMBO Journal</u> , 5:7:1577-1587.
	C26	Chan et al., (1991), "Induction of Interferon γ Production by Natural Killer Cell Stimulatory Factor: Characterization of the Responder Cells and Synergy with Other Inducers," <u>J. Exp. Med.</u> , pp. 869-879.
	C27	Chang et al., (1989), "Overview of Interleukin-2 as an Immunotherapeutic Agent," <u>Seminars in Surgical Oncology</u> , 5:385-390.
	C28	Chang et al., (1996), "A Point Mutation in Interleukin-2 that Alters Ligand Internalization," <u>Journal of Biological Chemistry</u> , 271:23:13349-13355.
	C29	Chaudhary et al., (1988), "Selective killing of HIV-infected cells by recombinant human CD4-Pseudomonas exotoxin hybrid protein," <u>Nature</u> , 335:370-372.
	C30	Chaudhary et al., (1989), "A recombinant immunotoxin consisting of two antibody variable domains fused to Pseudomonas exotoxin," <u>Nature</u> , 339:394-397.
	C31	Chen et al., (1997), "Eradication of Murine Bladder Carcinoma by Intratumor Injection of a Bicistronic Adenoviral Vector Carrying cDNAs for the IL-12 Heterodimer and Its Inhibition by the IL-12 p40 Subunit Homodimer," <u>Journal of Immunology</u> , 159:1:351-358.
	C32	Cheon et al., (1994), "High-affinity binding sites for related fibroblast growth factor ligands reside within different receptor immunoglobulin-like domains," <u>Proc. Natl. Acad. Sci. USA</u> , 91: 989-993.
	C33	Chuang et al., (1993), "Effect of new investigational drug taxol on oncolytic activity and stimulation of human lymphocytes," <u>Gynecol. Oncol.</u> , 49:291-298.
	C34	Cohen, S. L. et al., (1996), "Human leptin characterization," <u>Nature</u> , 382:589.
	C35	Cole et al., (1997), "Human IgG2 Variants of Chimeric Anti-CD3 Are Nonmitogenic to T Cells," <u>Journal of Immunology</u> , 159:3613-3621.
	C36	Collins et al., (1988), "Identification of Specific Residues of Human Interleukin 2 that Affect Binding to the 70-kDa Subunit (p70) of the Interleukin 2 Receptor," <u>Proc. Natl. Acad. Sci.</u> , 85:7709-7713.
	C37	Colombo et al., (1996), "Amount of Interleukin 12 Available at the Tumor Site is Critical for Tumor Regression," <u>Cancer Research</u> , 56:2531-2534.

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	C38	D'Amato et al., (1994), "Thalidomide is an inhibitor of angiogenesis," <u>Proc. Natl. Acad. Sci. USA</u> , 91:4082-4085.
	C39	D'Andrea et al., (1992), "Production of Natural Killer Cell Stimulatory Factor (Interleukin 12) by Peripheral Blood Mononuclear Cells," <u>J. Exp. Med.</u> , 176:1387-1398.
	C40	Ding et al., (1988), "Zinc-Dependent Dimers Observed in Crystals of Human Endostatin," <u>Proceedings of the National Academy of Sciences of USA</u> , 95:10443-10448.
	C41	Earnest et al., (1992), "Piroxicam and Other Cyclooxygenase Inhibitors: Potential for Cancer Chemoprevention," <u>J. Cell. Biochem. Supp.</u> , 161:156-166.
	C42	Eisenthal, (1990), "Indomethacin up-regulated the generation of lymphokine-activated killer-cell activity and antibody-dependent cellular cytotoxicity mediated by interleukin-2," <u>Cancer Immunol. Immunotherap.</u> 31:342-348.
	C43	Fell et al., (1991), "Genetic Construction and Characterization of Fusion Protein Consisting of a Chimeric F(ab') with Specificity for Carcinomas and Human IL-2," <u>The J. of Immunology</u> , 146:7:2446-2452.
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